

## **REMARKS**

Applicants respectfully request reconsideration of the present Application. Claims 32, 41, 42, 45, 46, and 48 have been amended herein. No new matter was introduced. Claims 32-52 are currently pending and believed to be in condition for allowance.

### **Objections – Double Patenting**

Claims 32-39, 41-47 and 49-52 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting for allegedly being unpatentable over claims 1-21 of copending Application No. 10/826,563. A terminal disclaimer is submitted herewith, thus rendering this objection moot.

### **Rejections based on 35 U.S.C. § 101**

Claims 49-52 were rejected under 35 U.S.C. § 101 for allegedly being directed toward non-statutory subject matter. Specifically, the Office contends claims 49-52 do not produce useful, tangible, and concrete results. To be useful, the claim must produce a result that is specific, substantial, and credible. *See* MPEP § 2106(a) (citations omitted). To be tangible, a process claim must produce “a real-world result.” MPEP § 2106(b). To be concrete, the claim must have a result that is reproducible. MPEP § 2106(c). Complying with the Office’s recommendation, independent claim 49 has been amended herein to recite the following feature: “outputting the inferred finding to a display for presentation in a user-readable format within a graphical user interface (GUI).” Applicants respectfully submit that claim 49 now recites a useful, tangible, and concrete result, and claims 50-52 inherit such a result. Accordingly, Applicants request withdrawal of the § 101 rejection of claims 49-52.

### **Rejections based on 35 U.S.C. § 112**

Claims 42-45 and 48 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter. Specifically, the Office stated the preambles of claims 42-45 and 48 recited methods but depended from the system recited in claim 41. Actually, claims 42, 45, and 48 previously recited methods while claims 43 and 44 recited systems. Applicants assume the Office inadvertently rejected claims 43 and 44. Claims 42, 45, and 48 have been amended herein to recite systems. Therefore, claims

42-45 and 48 now recite systems, and the § 112, second paragraph, rejection should be withdrawn.

**Rejections based on 35 U.S.C. § 103(a)**

The basic requirements of a *prima facie* case of obviousness are summarized in MPEP §§ 2143-2143.03. In particular, “the prior art reference (or references when combined) must teach or suggest all the claim limitations” in order to establish a *prima facie* case of obviousness. MPEP § 2143 (quoting *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). “If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.” MPEP § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

Claims 32-52 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious in the light of the following references.

- Pathak et al., Automatic Computation of Genetic Risk, 1043-0989/94, IEEE, 1994 (“Pathak”).
- Yan in view of Yan et al., PREVENTING ADVERSE DRUG EVENTS (ADEs): THE ROLE OF COMPUTER INFORMATION SYSTEMS, Drug Information Journal, Vol. 34, pp. 1247-60 (2000) (“Yan”).
- Roses, PHARMACOGENETICS AND THE PRACTICE OF MEDICINE, Nature, vol. 405, pp. 857-65 (June 15, 2000) (“Roses”).
- Wolf et al., PHARMACOGENETICS, British Medical Bulletin, vol. 55, no. 2, pp. 366-86 (1999) (“Wolf”).
- Kobrinski et al., A CONCEPT OF THE FEDERAL COMPUTER SYSTEM FOR FAMILIES WITH GENETIC DISEASES AND ITS PRACTICAL IMPLEMENTATION, Biomedical Engineering, vol. 31, no. 3, pp 172-74 (1997) (“Kobrinski”).

Due to the amendments made herein, claims 32-52 are allowable over the above references for at least the following reasons.

Generally speaking, at least one embodiment of the invention is directed towards receiving an electronic order for a patient, from a clinician, requesting a clinical agent or event and automatically calculating a likelihood the patient has a mutated gene. In other words, the calculated likelihood of a mutated gene is performed without a specific request by the clinician.

*See Specification*, ¶ 0028 (stating one embodiment “uses genetics based logic without a user actively seeking to apply genetics to the clinical situation. In other words, the system provides a user with an unsolicited inference of genetic finding(s) for a person.”). None of the cited references describe the same.

Independent claim 32 is directed to a computer-implemented method for determining and presenting the likelihood a person has a mutated form of a gene. As amended herein, the method comprises “receiving an electronic order from a clinician for at least one of a clinical agent or a clinical event for a person, wherein the electronic order **does not indicate a request to apply genetics** to the at least one of the clinical agent or the clinical event for the person.” The method further recites “**in response to the electronic order**, querying a first database to determine if the person has one or more genetic test results for the gene; [and] **in response to the electronic order**, obtaining the mode of inheritance for the gene.” Also, claim 32 recites “**without solicitation from a clinician**, querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene.”

The “querying” and “obtaining” steps of claim 32 are automatically performed based on a clinician’s request that does not request applying genetics to a patient’s application of genetics. In other words, the clinician requests information about a clinical agent or event and automatically receives information about the likelihood a patient has a mutated gene. The same is not described in any of the cited references.

The Office claims Pathak teaches the “receiving,” “querying,” and “obtaining” features of claim 32. Pathak does not, however, describe performing these method steps based on an electronic order that does not include a request to apply genetics to a clinical agent or event. At best, Pathak discusses a system for computing genetic risks based on family relationships, individual data, individual disease data, and disease parameters. *See Pathak*, p. 164, Figure 1. In fact, Pathak states its system “accepts as input the case data and the specification of the risk assessment task [i.e., assessment of genetic risk].” *Id.* at p. 164. Pathak also mentions “[t]he output of the system is the risk value of interest.” *Id.* Therefore, Pathak, at most, discloses a system that receives a request for a risk assessment about a patient’s genetics, calculates the risk, and outputs the risk assessment accordingly. Furthermore, the other cited references are also silent about receiving an electronic order without a request to apply genetics

and, based on the order, querying databases for genetic results to determine the likelihood a patient has a mutated gene. Therefore, the cited references do not teach or suggest each and every element of claim independent claim 32, as amended herein. Accordingly, Applicants respectfully request withdrawal of the § 103(a) rejection.

Independent claim 41 is directed to a computer system for determining and presenting the likelihood a person has a mutated form of a gene. The computer system comprises a receiving module, determining module, first querying module, obtaining module, second querying module, utilizing module, and presenting module. As amended herein, the receiving module is configured “for receiving an electronic order for at least one of a clinical agent or a clinical event for a person from a clinician, wherein the electronic order **does not indicate a request to apply genetics** to the at least one of the clinical agent or the clinical event for the person.” The determining module, as amended herein, is configured “for determining, **in response to receiving the electronic order**, whether the at least one of the clinical agent or the clinical event is associated with a gene.” Similarly, the first querying module is configured “for querying, **in response to the electronic order**, a first database to determine if the person has one or more genetic test results for the gene if the at least one of the clinical agent or the clinical event is associated with one or more genetic test results.” The obtaining module is configured “for obtaining, **in response to the electronic order**, the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene.” Finally, the presentation module is configured “for presenting the calculated likelihood the person has a mutated form of the gene to the clinician **without solicitation from the clinician for the calculated likelihood.**”

As previously stated, none of the cited references describe receiving an electronic order that does not indicate a request to apply genetic and, based on the electronic order, determining the likelihood a user has a gene mutation. Nor do the references describe modules capable of performing such a task. At best, Kobrinski discloses a system that stores medical documentation and can be configured to apply mathematical models for calculating the risk of genetic diseases. *See Kobrinski* at ¶¶ 2, 5, and 7. But Kobrinski fails to describe modules that are configured to perform the various functions recited in claim based on an receiving an electronic order that “does not indicate a request to apply genetics.” Nor does Kobrinski describe a module that presents the calculated likelihood a person has a mutated gene “without solicitation from the clinician for the calculated likelihood.” Thus, the cited references do not

teach or suggest each and every element of claim independent claim 41, as amended herein. Accordingly, Applicants respectfully request withdrawal of the § 103(a) rejection.

Independent claim 49, as amended herein, currently recites a method for determining and presenting the likelihood a person has a mutated form of a gene. As amended herein, the method comprises “receiving from a clinician an order for **a medication** for a person, wherein the clinician order **does not indicate a request about the genetics** of the person.” The method further recites “**in response to receiving the clinician order** for the medication, determining whether the order for medication is associated with a genetic finding; [and] **in response to receiving the electronic order**, obtaining the mode of inheritance for the gene.” Also, claim 32 has been amended to recite “**without solicitation from the clinician**, querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene.”

As previously stated, the cited references do not describe searching for genetic test results based on an clinician’s order, let alone an order for medication. Therefore, the cited references do not teach or suggest each and every element of claim independent claim 49, as amended herein. Accordingly, Applicants respectfully request withdrawal of the § 103(a) rejection.

Additionally, dependent claims 33-40, 42-48, 50, and 51 are also in condition for allowance based, at least in part, on their dependence, either directly or indirectly, from one of independent claims 32, 41, and 49. Accordingly, Applicants respectfully request withdrawal of the § 102(b) rejections thereto.

### **CONCLUSION**

For at least the reasons stated above, claims 32-52 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned at 816-474-6550 or [phoeller@shb.com](mailto:phoeller@shb.com) (such communication via email is herein expressly granted). If any additional fee is due for filing this response, the Commissioner is hereby authorized to charge any the additional amount required to Deposit Account No. 19-2112.

Respectfully submitted,

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